JS 44 (Rev. 09/11)

CIVIL COVER SHEET

The JS 44 civil coversheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS				DEFENDANTS					
Anna Blake				Organon USA, Inc	c., Organor	Pharmaceutic	cals USA, Inc.,	Orgai	non
				International, Inc.,	Akzo Nob	el NV, Schering	g-Plough Corp	oratio	n, and
(b) County of Regidence	of First Listed Plaintiff	alata Oassanha OA		Merck & Co., Inc. County of Residence	of Firet I jet	ed Defendant	Essex County	NI I	
(b) County of Residence of	CEPT IN U.S. PLAINTIFF CA	obb County, GA		County of Residence		-		INU	
(E)	CEPT IN O.S. PLAINTIFF CA	SES)		(IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.					ON OF
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(c) Attorneys (Firm Name	Address and Telephone Number	•ì		Attorneys (If Known)	•				
(c) Attorneys (Firm Name, A Scott D. Levensten, Esq.	The Levensten Law F	firm, P.C.		, , , , , ,		and the second			
1420 Walnut Street, Suite			•	•	*				
SDL@LevenstenLawFirn			1			T DIDETEC	<u> </u>		
II. BASIS OF JURISD	ICTION (Place an "X" i	n One Box Only)		TIZENSHIP OF I (For Diversity Cases Only)	RINCIPA	L PARTIES	(Place an "X" in Or and One Box for I		
☐ 1 U.S. Government	•			TF DEF				DEF	
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☐ 120 Marine ☐ 130 Miller Act	☐ 310 Airplane ☐ 315 Airplane Product	365 Personal Injury - Product Liability		of Property 21 USC 881		orawai ISC 157	☐ 400 State Reap ☐ 410 Antitrust	рогнош	nent
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☐ 150 Recovery of Overpayment	☐ 320 Assault, Libel &	Pharmaceutical	1			RTY RIGHTS			
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☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	370 Other Fraud		Act		k Lung (923)	Exchange		artios.
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle	371 Truth in Lending		20 Labor/Mgmt. Relations		C/DIWW (405(g))	☐ 890 Other Stat		tions
☐ 190 Other Contract ☐ 195 Contract Product Liability	Product Liability 360 Other Personal	380 Other Personal Property Damage		10 Railway Labor Act 51 Family and Medical	☐ 864 SSIE		891 Agricultur		itters
☐ 196 Franchise	Injury	☐ 385 Property Damage		Leave Act	003 1031	(100(g))	☐ 895 Freedom		
	☐ 362 Personal Injury -	Product Liability	□ 79	0 Other Labor Litigation			Act		
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☐ 240 Torts to Land ☐ 245 Tort Product Liability	443 Housing/ Accommodations	530 General 535 Death Penalty	: EMSSSHEE	IMMIGRATION	_	/SC 7009	State State		
290 All Other Real Property	☐ 445 Amer. w/Disabilities -	☐ 540 Mandamus & Ot	her 🗆 46	52 Naturalization Applicatio					
	Employment	550 Civil Rights		53 Habeas Corpus - Alien Detainee					
	☐ 446 Amer. w/Disabilities - Other	555 Prison Condition 560 Civil Detainee -	¹	(Prisoner Petition)					
	☐ 448 Education	Conditions of	□ 46	55 Other Immigration					
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		tute under which you a	are filing ((Do not cite jurisdictional s	tatutes unless a	liversity):			
VI. CAUSE OF ACTIO	ON 28 USC 1332 Brief description of ca			·		· · · · · · · · · · · · · · · · · · ·			
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VII. REQUESTED IN		IS A CLASS ACTIO		EMAND \$		CHECK YES only	if demanded in co	omplain	ıt;
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FOR OFFICE USE ONLY									
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Case 2:12-cv-06007-LDD Document 1 Filed 10/22/12 Page 2 of 32 UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM t assignment to appropriate calendar.	to be used by counsel to indicate the category of the case for the purpose of
Address of Plaintiff: Anna Blake, 1019 Franklin Rd, SE,	Ast. 31-L, Marietta, 6A 30067
Address of Defendant: Organon USA, Inc., 56 Livingston	Ave, Roseland, NJ 07068
	and Essex County, NJ
Place of Accident, Incident or Transaction: Cobb County, 679 6 (Use Reverse Side Fo	
Does this civil action involve a nongovernmental corporate party with any parent corporatio (Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1	
Does this case involve multidistrict litigation possibilities?	Yes No□
RELATED CASE, IF ANY:	250V2 - A L2 -
Case Number: MDL 1964 Judge Rodney Sippel-USDO	EDMODate Terminated: Active
Civil cases are deemed related when yes is answered to any of the following questions:	
1. Is this case related to property included in an earlier numbered suit pending or within one	e year previously terminated action in this court?
	Yes□ No□
2. Does this case involve the same issue of fact or grow out of the same transaction as a pric action in this court?	or suit pending or within one year previously terminated
actor in this voice.	Yes□ No□
3. Does this case involve the validity or infringement of a patent already in suit or any earlier	er numbered case pending or within one year previously
terminated action in this court?	Yeş□ No□
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil ri	ghts case filed by the same individual?
CIVIL: (Place ✔ in ONE CATEGORY ONLY)	
A. Federal Question Cases:	B. Diversity Jurisdiction Cases:
1. □ Indemnity Contract, Marine Contract, and All Other Contracts	1. Insurance Contract and Other Contracts
2. □ FELA	2. Airplane Personal Injury
3. □ Jones Act-Personal Injury	3. □ Assault, Defamation
4. □ Antitrust	4. □ Marine Personal Injury
5. □ Patent	5. Motor Vehicle Personal Injury
6. □ Labor-Management Relations	6. □ Other Personal Injury (Please specify)
7. □ Civil Rights	7. Products Liability
8. □ Habeas Corpus	8. Products Liability — Asbestos
9. □ Securities Act(s) Cases	9. □ All other Diversity Cases
10. □ Social Security Review Cases	(Please specify)
11. □ All other Federal Question Cases	
(Please specify)	
ARBITRATION CER (Check Appropriate	Category)
I, counsel of record do hereby ce Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge as	
\$150,000.00 exclusive of interest and costs;	
Relief other than monetary damages is sought.	761 04 70:22
DATE: 10-22-12 SDL 3	
Attorney-at-Law NOTE: A trial de novo will be a trial by jury only if	Attorney I.D.# there has been compliance with F.R.C.P. 38.
I certify that, to my knowledge, the within case is not related to any case now pending	or within one year previously terminated action in this court

except as noted above.

Case 2:12-cv-06007-LDD Document 1 Filed 10/22/12 Page 3 of 32

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

Anna Blake		:	CIVIL ACTION		
v.		:			
Organon USA, In	c., et al.	:	NO.		
plaintiff shall complete a Cas filing the complaint and serve side of this form.) In the ex- designation, that defendant sl	e Management To a copy on all defe- vent that a defendall, with its first ties, a Case Mana	cack Designation andants. (See § 1: lant does not agrappearance, subn gement Track De	ction Plan of this court, couns Form in all civil cases at the ti 03 of the plan set forth on the rece with the plaintiff regarding it to the clerk of court and set esignation Form specifying the	me of everse g said eve on	
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(a) Habeas Corpus – Cases b	rought under 28 l	J.S.C. § 2241 thr	ough § 2255.	, ().,	
(b) Social Security – Cases re and Human Services deny	equesting review ying plaintiff Soc	of a decision of the	he Secretary of Health fits.	().	
(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ()					
(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos.					
(e) Special Management – C commonly referred to as the court. (See reverse si management cases.)	complex and that	need special or in	ntense management by	()	
(f) Standard Management –	Cases that do not	fall into any one	of the other tracks.	X	
10-22-12 Date					
215-545-5600	215-545	5156	SDL@LevenstenLawFirm	n. Com	
Telephone	FAX Numb	er	E-Mail Address		

(Civ. 660) 10/02

SCOTT D. LEVENSTEN, ESQUIRE The Levensten Law Firm, P.C. 1420 Walnut Street, Suite 1500 Philadelphia, PA 19102 Phone: 215.545.5600

Fax: 215.545.5156

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

ANNA BLAKE,

Plaintiff,

CIVIL ACTION No.

v.

ORGANON USA, INC., ORGANON PHARMACEUTICALS USA, INC., ORGANON INTERNATIONAL, INC., AKZO NOBEL NV, SCHERING-PLOUGH CORPORATION, and MERKC & CO., INC.

Defendants.

COMPLAINT

Demand for Jury Trial

COMPLAINT FOR DAMAGES

COMES NOW the Plaintiff, ANNA BLAKE, by and through the undersigned attorneys, and file this Complaint for Damages against the above-named Defendants, ORGANON USA, INC., ORGANON PHARMACEUTICALS USA, INC., ORGANON INTERNATIONAL, INC., AKZO NOBEL NV, SCHERING-PLOUGH CORPORATION, and MERCK & CO., INC. for good cause states the following:

1. This is an action for personal injuries suffered by Plaintiff as a proximate result of Plaintiff being prescribed and using the defective and unreasonably dangerous birth control pharmaceutical known as NUVARING, which is and was, at all times relevant to this action, manufactured, designed, tested, packaged, labeled, marketed, advertised, distributed, prescribed, and sold by Defendants named and identified herein. Plaintiff alleges as follows:

PARTIES

- 2. Plaintiff ANNA BLAKE is, and at all times material hereto was, an adult citizen and resident of the State of Georgia, residing at 1019 Franklin Road Southeast, Apartment 31L, Marietta, Georgia 30067. Plaintiff was prescribed and began using the NUVARING in March 2010 and continued using the NUVARING according to label instructions until November 2010, when she suffered deep vein thrombosis, blood clots and a pulmonary embolism. Plaintiff continues to suffer residual physical harm from the deep vein thrombosis, blood clots and pulmonary embolism she suffered as a proximate result of her use of the defective NUVARING.
- 3. Defendant, ORGANON USA, INC., is a New Jersey corporation which has its principal place of business located at 56 Livingston Avenue, Roseland, New Jersey 07068.
- 4. Defendant, ORGANON USA, INC., is a global pharmaceutical company engaged in the business of creating, manufacturing, marketing, distributing, labeling, researching, developing and selling medicines in the field of women's health, including the contraceptive, NUVARING.
 - 5. Defendant, ORGANON PHARMACEUTICALS USA, INC., is a foreign

corporation authorized and actually transacting business in the State of New Jersey, with its principal place of business located at 56 Livingston Avenue, Roseland, New Jersey 07068.

- 6. Defendant, ORGANON PHARMACEUTICALS USA, INC., is a global pharmaceutical company engaged in the business of creating, manufacturing, marketing, distributing, labeling, researching, developing and selling medicines in the field of women's health, including the contraceptive, NUVARING.
- 7. Based on information and belief, ORGANON and its related entities, including Organon Biosciences, NV and Akzo Novel NV, were acquired by Schering-Plough on November 19, 2007.
- 8. Defendant, ORGANON INTERNATIONAL, INC., is a foreign corporation authorized and actually transacting business in the State of New Jersey, with its principal place of business located at 56 Livingston Avenue, Roseland, New Jersey 07068.
- 9. Defendant, ORGANON INTERNATIONAL, INC., is a global pharmaceutical company engaged in the business of creating, manufacturing, marketing, distributing, labeling, researching, developing and selling medicines in the field of women's health, including the contraceptive, NUVARING.
- 10. Defendant AZKO NOBEL NV is a global Fortune 500 Company incorporated and existing under the laws of The Netherlands.
- 11. Defendant AZKO NOBEL NV, individually and through its wholly owned subsidiaries, including Defendants herein, and the trading of its stock on NASDAQ regularly transacts or solicits business, engages in a persistent course of conduct, and derives substantial revenue from goods used or consumed in the Commonwealth of Pennsylvania.

- 12. Defendant AZKO NOBEL NV, individually and through its wholly owned subsidiaries, including Defendants herein, is a company engaged in the business of creating, manufacturing, marketing distributing, labeling, researching, developing and selling medicines in the field of women's health, including the contraceptive, NUVARING.
- 13. Defendant SCHERING-PLOUGH CORPORATION is a corporation authorized and actually transacting business in the Commonwealth of Pennsylvania, with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.
- 14. Defendant SCHERING-PLOUGH CORPORATION acquired the above-named Defendants in 2007 and assumed the liabilities attendant thereto, and has its principal place of doing business in New Jersey.
- 15. In 2008, Defendant SCHERING-PLOUGH CORPORATION acquired Defendant ORGANON PHARMACEUTICALS USA, INC.; caused it to be dissolved as a corporation; and made it a subsidiary. In so doing, Defendant SCHERING-PLOUGH CORPORATION assumed the liabilities of ORGANON PHARMACEUTICALS USA, INC., as pleaded in this complaint.
- 16. In 2009, Defendant Merck & Co., Inc., which has its principal place of doing business in New Jersey, acquired Defendant SCHERING-PLOUGH CORPORATION and assumed the liabilities attendant to both SCHERING-PLOUGH CORPORATION and the previously named ORGANON Defendants, plus became liable for injuries which the said product caused after it took control of it.
 - 17. At all times herein mentioned, "Defendants" include all named Defendants.
- 18. At all times relevant to this Complaint, each of the Defendants was the agent, principal, servant, partner, employer, employee, representative, successor in interest, predecessor

in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy, and joint venture and rendered substantial assistance and encouragement to the other Defendants, and condoned and ratified the conduct and omission of each Defendant, with full knowledge and awareness that their acts, omissions, and conduct constituted a breach of duty owed to Plaintiff.

- 19. At all times relevant to this Complaint, there exists and/or existed, a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter-ego of the other certain Defendants and exerted control over those Defendants.

 Adherence to the fiction of the separate existence of these certain Defendants as an entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud, and promote injustice.
- At all times herein mentioned, the officers and directors of the Defendants named herein participated in, authorized and directed the production and promotion of NUVARING when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of NUVARING and thereby actively participated in, condoned, and ratified the tortious conduct which proximately resulted in the injuries suffered by Plaintiff.
- 21. At all times relevant to this Complaint and with respect to this plaintiff,

 Defendants acted individually and through their respective agents, servants, or employees in the

 course and scope of their respective employment, including without limitation the other

 Defendants.

- 22. Defendants are, and were at all relevant times, duly authorized to conduct business in the Commonwealth of Pennsylvania.
 - 23. Defendants have transacted business in the Commonwealth of Pennsylvania.
- 24. Defendants regularly conduct and solicit business within the Commonwealth of Pennsylvania.
- 25. At all relevant times, Defendants, through their agents, servants, and employees, were the designers, manufacturers, marketers, advertisers, distributors, and sellers of NUVARING.
- 26. Defendants, either directly or through their agents, servants, and employees, do business in the Commonwealth of Pennsylvania, and at all relevant times, have sold and distributed NUVARING in the Commonwealth of Pennsylvania.
- 27. Defendants derive substantial revenue from goods used or consumed in the Commonwealth of Pennsylvania.
- 28. Defendants expected, or should have expected, that their actions could or would have consequences within the Commonwealth of Pennsylvania.

JURISDICTION AND VENUE

29. This Court has jurisdiction pursuant to 28 U.S.C. § 1332 because complete diversity exists because Plaintiff is a citizen of the State of Georgia which is different from the State where the defendants are incorporated and have their principal places of business, and the amount in controversy, exclusive of interest and costs, exceeds seventy-five thousand dollars (\$75,000.00).

- 30. Venue is proper within this District pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this district and the defendant, at all times relevant times, conducted substantial business in this District.
- 31. The damages recoverable in this action exceed the sum of one hundred fifty thousand dollars (\$150,000.00); thus, this case is not appropriate for compulsory arbitration under Local Civil Rule 53.2.
- 32. Upon information and belief, at all relevant and material times hereto, the Defendants designed, manufactured, sold, tested, marketed, advertised, promoted, and/or distributed the birth control pharmaceutical NUVARING within the jurisdiction and venue of this Court.
- 33. Upon information and belief, at all relevant and material times hereto, the Defendants engaged in substantial activities (e.g. planning meetings, strategy sessions, etc.) in furtherance of the design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the birth control pharmaceutical NUVARING within the jurisdiction and venue of this Court.

FACTUAL ALLEGATIONS COMMON TO ALL COUNTS AS TO NUVARING

- 34. Plaintiff realleges and incorporates herein by this reference all of the paragraphs of this Complaint and further alleges, as follows:
- 35. The United States Food and Drug Administration approved NUVARING in October 2001 as a contraceptive (birth control) vaginal ring used to prevent pregnancy. Subsequent to FDA approval, NUVARING was and continues to be widely advertised and marketed by Defendants as a safe and effective contraceptive.

- 36. Defendants marketed, and continue to market, NUVARING as the first hormonal vaginal contraceptive ring.
- 37. Defendants marketed, and continue to market, NUVARING as providing the same efficacy as birth control pills in preventing pregnancy, but with more convenience than birth control pills because it is inserted in the vagina for three consecutive weeks with the fourth week being "ring free." The hormones contained within the ring are absorbed continuously directly into the blood stream through the vaginal wall.
- 38. NUVARING is a combination contraceptive containing a progestin, etonogestrel and an estrogen component, ethinyl estradiol.
- 39. Over a three week period, the NUVARING releases 15 micrograms of ethinyl estradiol and 120 micrograms of etonogestrel per day.
- 40. Prior to and during the time that Plaintiff Anna Blake utilized NUVARING,
 Defendants marketed, promoted, and advertised the NUVARING product to physicians and to
 the public as more effective and safer than the oral contraceptive pill, at a time that the
 Defendants had actual and/or constructive knowledge that the NUVARING was less safe than
 the pill.
- 41. Prior to and during the time that Plaintiff Anna Blake utilized NUVARING,
 Defendants marketed the benefits of their product as a low estrogen dose contraceptive, but failed
 to warn consumers that the NUVARING contains a relatively high does of etonogestrel, which is
 a metabolite of the "third generation" progestin desogestrel (DSG) and upon information and
 belief is associated with increased risks of, *inter alia*, cardiovascular thromboembolic injury.
 - 42. Defendants distributed information in the form of, but not limited to reports, press

releases, advertising campaigns, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealed the truth regarding the dangers of the use of NUVARING to the public, including Plaintiff, the medical community, and the FDA. Based upon Defendants' representations regarding the safety and efficacy of the birth control ring, Plaintiff was prescribed and used the NUVARING beginning in March 2010 until November 2010. Plaintiff would not have used the NUVARING if she had been informed of the true and accurate risks of serious harm associated with the use of Defendants' birth control ring. Plaintiff was never informed of the dangers of the birth control ring until after she suffered deep vein thrombosis, blood clots and pulmonary embolism.

- 43. Defendants' label did not contain language to adequately explain the actual and/or real risk of cardiovascular events, including without limitation, blood clots, pulmonary emboli, stroke and thromboembolism associated with the use and insertion of the NUVARING.
- 44. All of Defendants' statements failed to adequately warn the medical community, Plaintiff, and other consumers of the NUVARING, of the serious risks associated with the use of the NUVARING, although Defendants knew and/or should have known of the serious health risks associated with use of NUVARING.
- 45. Prior to March 2010, Defendants knew of should have known that use of the NUVARING created a higher risk of pulmonary embolism than oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.
- 46. At the time Plaintiff used NUVARING from March 2010 until November 2010, Defendants knew and/or should have known that the use of NUVARING created an increased risk to consumers of serious personal injury, including, but not limited to pulmonary embolism,

blood clots, stroke, and venous thromboembolism and even death.

- 47. Defendants failed to warn the medical community, Plaintiff, and other consumers of the NUVARING, of the serious risks associated with use of the NUVARING before Plaintiff used the product, although Defendants knew and/or should have known of the serious health risks associated with use of NUVARING.
- 48. Had Plaintiff, Anna Blake, known the real and/or actual risks and dangers associated with NUVARING, she would not have used NUVARING and would not have suffered deep vein thrombosis, blood clots, or pulmonary embolism and the residual health effects resulted therefrom.
- 49. As a direct and proximate result of Plaintiff's use of NUVARING, Plaintiff suffered significant harm, conscious pain and suffering, physical injury and bodily impairment, including but not limited to suffering from a cardiovascular injury, including without limitation deep vein thrombosis, blood clots, and pulmonary embolism, which has caused permanent physical effect, and which will continue in the future to cause her physical effects and damage throughout her lifetime.
- 50. As a further, direct and proximate result of Plaintiff's use of NUVARING,
 Plaintiff suffered significant mental anguish and emotional distress, was in fear for her life, and
 will continue in the future to suffer physical limitations, pain, injury, damages, harm and mental
 and emotional distress.
- 51. Plaintiff Anna Blake has also incurred medical expenses and other economic harm including lost earnings, loss of earning capacity, and will continue to incur expenses and lost earnings in the future, as a direct and proximate result of her use of NUVARING.

CLAIMS FOR RELIEF

Count I: Negligence

- 52. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.
- 53. Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and/or selling NUVARING. This duty included the duty not to introduce a pharmaceutical device into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects.
- 54. At all relevant times to this action, Defendants owed a duty to properly warn Plaintiff, Physicians, and the Public of the risks, dangers and adverse side effects of NUVARING.
- 55. Defendants breached their duties by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and/or selling of NUVARING, including:
- a. failing to use due care in the preparation and development of NUVARING to prevent the aforementioned risk of injuries to individuals when the ring was inserted;
- b. failing to use due care in the design of NUVARING to prevent the aforementioned risk of injuries to individuals when the ring was inserted;
- c. failing to conduct adequate pre-clinical testing and research to determine the safety of NUVARING;

- d. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of NUVARING, while defendant knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of NUVARING, and that such surveillance would be necessary for a due diligence program that would alert defendant to the need to change the ring's warnings or to withdraw it from the market altogether;
- e. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, physicians, consumers, the medical community, and the FDA;
- f. failing to accompany NUVARING with proper warnings regarding all possible adverse side effects associated with the use of the same;
- g. failing to use due care in the manufacture, inspection, and labeling of NUVARING to prevent the aforementioned risk of injuries to individuals who used the ring;
- h. failing to use due care in the promotion of NUVARING to prevent the aforementioned risk of injuries to individuals when the ring was inserted;
- i. failing to use due care in the sale and marketing of NUVARING to prevent the aforementioned risk of injuries to individuals when the ring was inserted;
- j. failing to use due care in the selling of NUVARING to prevent the aforementioned risk of injuries to individuals when the ring was inserted;
- k. failing to provide adequate and accurate training and information to the sales representatives who sold the ring;

- 1. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of NUVARING;
 - m. being otherwise reckless, careless and/or negligent.
- 56. Despite the fact that Defendants knew or should have known that NUVARING caused unreasonable and dangerous side effects which many users would be unable to remedy by any means, Defendants continued to promote and market NUVARING to consumers, including Plaintiff, when safer and more effective methods treatment were available.
- 57. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.
- 58. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

Count II: Breach of Express Warranty

- 59. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.
- 60. The Defendants expressly represented to Plaintiff, her physicians, other consumers and the medical community that NUVARING was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, particularly any unwarned-of side effects, and that it was adequately tested.
 - 61. These warranties from the Defendants came in the form of:
- a. Defendants' public written and verbal assurances of the safety and efficacy of NUVARING;
- b. Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for NUVARING, which failed to warn of the risk of injuries inherent to the insertion of NUVARING;
- c. Verbal and written assurances made by Defendants regarding NUVARING, and downplaying the risk of injuries associated with the ring;
- d. False and misleading written information, supplied by Defendants, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing NUVARING during the period of Plaintiff's insertion of NUVARING, and;

- e. advertisements.
- 62. The documents referred to above were created by and at the direction of Defendants.
- 63. Defendants knew or had reason to know that NUVARING, did not conform to these express representations in that NUVARING is not as safe and/or as effective as represented, and that NUVARING is associated with serious adverse side effects.
- 64. NUVARING did not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, including unwarned-of side effects, and causes severe and permanent injuries.
- 65. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.
- 66. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.
 - 67. Defendants' conduct was committed with knowing, conscious, wanton,

willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

Count III: Breach of Implied Warranty

- 68. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.
- 69. At all relevant and material times hereto, the Defendants designed, tested, manufactured, packaged, marketed, distributed, promoted, and/or sold NUVARING.
- 70. At all relevant times, Defendants knew of the use for which NUVARING, was intended and impliedly warranted the ring was of merchantable quality and safe and fit for such use.
- 71. NUVARING was not of merchantable quality; nor fit for its intended use, because it causes increased risk of serious injury and death, and other serious and harmful adverse health effects.
- 72. Defendants breached the implied warranty that NUVARING was of merchantable quality and fit for such use in violation of Pennsylvania law.
- 73. Defendants were aware of the uses and indications that consumers, including Plaintiff, would use NUVARING.

- 74. Plaintiff, her physicians and the medical community reasonably relied upon

 Defendants' judgment and expertise to sell them or allow them to prescribe NUVARING only if
 the ring was indeed of merchantable quality and safe and fit for its intended use.
- 75. Plaintiff, her physicians, consumers and the medical community, reasonably relied upon Defendants' implied warranty for NUVARING.
- 76. NUVARING reached consumers, including Plaintiff, without substantial change in the condition in which it was manufactured, advertised, promoted, and/or sold by Defendants.
- 77. Defendants breached their implied warranty to consumers, including Plaintiff, as neither NUVARING was of merchantable quality or safe and fit for its intended use.
- As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.
- 79. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

Count IV: Fraudulent Misrepresentation & Concealment

- 80. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.
- 81. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of NUVARING and their intentional dissemination of promotional and marketing information about NUVARING for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with the ring.
- 82. Defendants made fraudulent affirmative misrepresentations regarding NUVARING in the following particulars:
- a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that NUVARING had been tested and found to be safe and; and
- b. Defendants represented that NUVARING was safer than other alternative medications.

- 83. Defendants made affirmative misrepresentations; and fraudulently, intentionally and/or recklessly concealed material adverse information regarding the safety and effectiveness of NUVARING.
- 84. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or had reason to know that NUVARING had defects and was unreasonably dangerous and was not what Defendants had represented to the medical community, the FDA and the consuming public, including Plaintiff.
- 85. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of NUVARING and other serious health risks. Furthermore, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of NUVARING in order to increase sales.
- 86. The representations and concealment were undertaken by Defendants with an intent that doctors and patients, including Plaintiff, rely upon them.
- 87. Defendants' representations and concealments were undertaken with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of NUVARING.
- 88. Defendants' fraudulent representations evinced their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.
- 89. Plaintiff's physician and Plaintiff relied on and were induced by Defendants' misrepresentations, omissions, and/or active concealment of the dangers of NUVARING in selecting treatment.

- 90. Plaintiff and the treating medical community did not know that the representations made by Defendants were false and were justified in relying upon Defendants' representations.
- 91. Had Plaintiff been aware of the increased risk of side effects associated with NUVARING and the relative efficacy of NUVARING compared with other readily available medications, Plaintiff would not have taken NUVARING as she did.
- 92. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.
- 93. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

Count V: Fraud

- 94. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.
- 95. At all relevant times, Defendants concealed or omitted material information regarding the safety of NUVARING from consumers, including Plaintiff, and the medical community.
- 96. Defendants knew, or were reckless in not knowing, that NUVARING posed significant risks of causing severe and permanent injuries, and elected not to advise the medical community, Plaintiff, or other consumers of NUVERING's risks, and consequently placed its profits above the safety of Plaintiff and other consumers.
- 97. In their representations, Defendants fraudulently concealed and intentionally omitted material information about NUVARING's dangers from consumers, including Plaintiff.
- 98. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or had reason to know that NUVARING had defects and was unreasonably dangerous and was not what Defendants had represented to the medical community, the FDA and the consuming public, including Plaintiff.
- 99. Defendants omitted, suppressed and/or willfully concealed material facts concerning the dangers and risk of injuries associated with the use of NUVARING and other serious health risks. Furthermore, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of NUVARING in order to increase sales.

- 100. Defendants had sole access to material facts concerning the dangers and unreasonable risks of NUVARING.
- 101. Defendants' representations and concealments were undertaken with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of NUVARING.
- 102. Defendants' fraudulent representations evinced their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.
- 103. Defendants were under a duty to disclose to Plaintiff, other consumers, and the medical community the defective nature of NUVARING, and the risks and dangers associated with its use.
- 104. Plaintiff and the treating medical community did not know that the representations made by Defendants were false and were justified in relying upon Defendants' representations.
- 105. Had Plaintiff been aware of the increased risk of side effects associated with NUVARING and the relative efficacy of NUVARING compared with other readily available medications, Plaintiff would not have taken NUVARING as she did.
- 106. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical

losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

107. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

Count VI: Negligent and Reckless Misrepresentation

- 108. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.
- 109. Defendants negligently and/or recklessly represented to Plaintiff's physicians, and other persons and professionals on whom it was known by Defendants that Plaintiff would rely, as well as the public at large, that the NUVARING was safe to insert and that the utility of this product outweighed any risk in use for their intended purposes.
- 110. Defendants negligently and/or recklessly failed to disclose to Plaintiff, and others for the benefit of Plaintiff, important safety and injury information, thereby suppressing material facts about the ring, while having a duty to disclose such information, which duty arose from their actions of making, marketing, promoting, distributing and/or selling pharmaceutical

products to Plaintiff and others, Defendants further led Plaintiff to rely upon the safety of the product in its use.

- 111. The false representations of Defendants were negligently and recklessly made, in that NUVARING in fact caused injury, was unsafe, and the benefits of use were outweighed by the risk.
- 112. Defendants, individually and collectively, committed acts of negligent misrepresentation and negligent concealment by suppressing material facts relating to the dangers and injuries associated with, and caused by, the use of the subject ring.
 - 113. Defendants knew or should have known that their representations were false.
- 114. Defendants made such false, negligent and /or reckless representations with the intent or purpose that Plaintiff and Plaintiff's physicians would rely upon such representations, leading to the use of the subject ring by Plaintiff.
- 115. As a direct and proximate result of Defendants' negligent and reckless misrepresentations or concealment of facts, upon which Plaintiff reasonably relied, Plaintiff suffered injuries and sustained damages for which Defendants are liable.
- 116. As a direct result of the negligent and reckless misrepresentation of Defendants, Plaintiff has sustained serious injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization,

physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, cost or suit, attorneys' fees and all such other relief as the Court deems proper.

Count VII: Unjust Enrichment

- 117. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein.
- 118. At all times material hereto, the Defendants manufactured, distributed, advertised, promoted, and/or sold NUVARING.
- 119. Plaintiff paid for NUVARING for the purposes prescribed by her physicians in receiving medical treatment.
- 120. Defendants have accepted payment, either directly or indirectly, from Plaintiff for the purchase of NUVARING.
- 121. Plaintiff did not receive the safe and effective pharmaceutical product for which she paid.
- 122. It is inequitable and unjust for Defendants to retain this money because the Plaintiff did not in fact receive the product Defendants represented NUVARING to be.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

Count VIII: Plaintiff's Damages

- 123. Plaintiff incorporates by reference the preceding paragraphs as if they were fully set forth herein.
- 124. As a result of the individual, combined and concurring acts and omissions of Defendants as set forth herein above, each above-named Defendant, caused or contributed to cause the following injuries to Plaintiffs:
- a. Plaintiff has been caused to suffer physical injury, past, present and future pain and suffering, disability, impairment, lost capacity to enjoy life, mental anguish, and lost earnings in an amount to be proven at trial;
- b. Plaintiff has been caused to incur medical expenses and will in the future incur medical expenses an amount to be proven at trial;
- c. Plaintiff has been caused to undergo medical treatment and monitoring and will be required to undergo medical treatment and monitoring for the rest of Plaintiff's life an amount to be proven at trial;

Count IX: Punitive Damages

- 125. Plaintiff incorporates by reference the preceding paragraphs as if they were fully set forth herein.
- 126. The conduct of each Defendant, as set forth herein above was intentional, willful, wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise

the presumption of a conscious indifference to the consequences in that each Defendant acted only out of self interest and personal gain. Such conduct evidences a specific intent to cause harm to Plaintiff as provided under applicable and governing law. Accordingly, punitive damages should be imposed against each Defendant to punish and deter each Defendant from repeating or continuing such unlawful conduct.

- 127. The Plaintiff is entitled to punitive damages because the Defendant's failure to warn was reckless and without regard for the public's safety and welfare. The Defendant misled both the medical community and the public at large, including the Plaintiff, by making false representation about the safety of NUVARING. Defendant downplayed, understated and/or disregarded its knowledge of the serious and permanent side effects and risks associated with the use of NUVARING despite available information demonstrating that the ring was likely to cause serious and even fatal side effects to users.
- 128. Defendant was or should have been in possession of evidence demonstrating that NUVARING caused serious side effects and adverse reactions. Nevertheless, Defendant continued to market NUVARING by providing false and misleading information with regard to safety and efficacy.
- 129. Defendant failed to provide warnings that would have dissuaded physicians from prescribing NUVARING and consumers from purchasing and consuming the ring, thus depriving physicians and consumers, including the Plaintiff, from weighing the true risks against the benefits of prescribing and/or purchasing and consuming NUVARING.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory,

treble and punitive damages, together with interest, cost or suit, attorneys' fees and all such other relief as the Court deems proper.

Request for Relief

WHEREFORE, Plaintiff prays:

- a. That process issue according to law;
- b. That each Defendant be served with a copy of Plaintiff's Complaint and show cause
- c. why the prayers for relief requested by Plaintiff herein should not be granted;
 - d. That Plaintiff be granted a trial by jury in this matter;
- e. That the Court enter a judgment against each Defendant, jointly and severally, for all
 - f. general and compensatory damages allowable to Plaintiff;
- g. That the Court enter a judgment against each Defendant, jointly and severally, for all special damages allowable to Plaintiff;
- h. That the Court enter a judgment against each Defendant serving to award Plaintiff punitive damages;
- i. That the Court enter a judgment against each Defendant, jointly and severally, for all other relief sought by Plaintiff under this Complaint;
 - j. That the costs of this action be cast upon Defendants; and
 - k. That the Court grants Plaintiff such further relief that the Court deems just

and appropriate.

Respectfully submitted this 22nd day of October, 2012.

SCOTT D. LEVENSTEN, ESQUIRE

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Philadelphia, PA 19102 Phone: 215.545.5600 Fax: 215.545.5156

Attorneys for Plaintiff

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Respectfully submitted this 22nd day of October, 2012.

SCOTT D. LEVENSTEN, ESQUIRE

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